

Paper No. 18

APPEAL NO:

92-3627

SERIAL NUMBER:

07/542,232

APPELLANTS:

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NED R. SIEGEL and PETER G. MILNER

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RESPONSE TO REMAND

This case was remanded to the Examiner, Paper No. 17, for a determination of whether claims 4 and 6 satisfy the enablement requirement of 35 USC § 112, first paragraph. Specifically, the Board directed the Examiner's attention to the comment made by the court in *In re Deuel*, 34 USPQ 1210 (Fed. Cir. 1995) regarding the adequacy of support in the disclosure for claims 4 and 6, *Deuel* at 1216.

Claims 4 and 6 are directed to a purified and isolated DNA sequence encoding recited sequences of 168 amino acids. The genus of DNA sequences encoding each recited amino acid sequence would have been immediately envisaged by one of skill in the art given the contemporary knowledge in this art at the time of filing because the coding key had long been well known. Assuming an average degeneracy in the code of three codons per amino acid, the genus comprises millions of species, each 504 nucleotides long. It would have been trivial to write out any one of the actual formulas in the nucleotide sequence by using the genetic code as the key to encode the amino acids. Accordingly, the disclosure satisfies the adequate written description requirement. At that time, synthesis of any one of those formulas, the actual DNA compositions encoding a particular 168 amino acid sequence, would not have required special guidance because synthesis and purification of a DNA having 504 nucleotides was being done with predictable results, reproducible chemical synthesis having been mechanized well before Applicants' filing date. Any desired sequence of this length could have been mail ordered

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from a commercial synthesizing service of the time, e.g., the Stratagene company. A routine and more economically efficient alternative would have been mail ordering several overlapping fragments, about 100 nucleotides each, of the sequence and its complement, followed by enzymatic assembly/fill in to make the complete sequence. Accordingly, the disclosure, supplemented with the routine procedures known to those working in this art at the time, adequately teaches how to make the compounds. The disclosure does not appear to contain a positive recitation of how to use the generic compounds. Example 2, pages 17-18, teaches how to use the naturally occurring sequence as a hybridization probe. Some of the generic compounds that are similar to the native sequence could be similarly used, particularly when based on preference codons. Given the disclosed relationship between the protein and the DNA, it would have been apparent to the skilled artisan at the time of filing that virtually all members of the DNA genus could be used to express the protein recombinantly. While there might be some species within the genus that are inoperable, Applicants are not required to exhaustively demonstrate operability to comply with the statute. Accordingly, the disclosure adequately teaches how to use the claimed genus.

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Respectfully submitted,

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Stephen Walsh, Ph.D.
Primary Examiner
Group 1800

SW August 17, 1995

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